**Radiology Pre-IRB Determination Checklist**

*Please complete this checklist when determining if the research you are proposing requires a submission to UNM HS Institutional Review Board. Please check all that apply.*

PI Name:

Proposed Study Title:

|  |
| --- |
| **Human Subject** |
|[ ]  Is this research attempting to prove or disprove a hypothesis? |
|[ ]  Does this research have any direct, ***immediate*** impact on patient clinical outcomes? |
|[ ]  Are study subjects receiving clinical interventions and/or randomized into different intervention or control groups? |
|[ ]  Does the research necessitate the storage and maintenance of patient clinical information or PHI to determine if outcomes prove or disprove a hypothesis?\* |
|[ ]  Is the researcher attempting:Physical/clinical intervention on a living study subject for data collection? ORCommunicating directly with study subjects for data collection? |
| *If* ***any*** *of boxes in this section are checked, this is likely Human Subject research. Please send research idea or protocol to Radiology Research Coordinator for review.* |
| **QA/QI/QC Research** |
|[ ]  Does this research attempt to use existing scientific knowledge or imaging techniques to improve clinical outcomes?\*\* |
|[ ]  Does this research aim to improve or change institutional imaging practices for ***future*** improved clinical outcomes? |
|[ ]  Does this research intend to evaluate current established standards, programs, processes, or systems within a clinical setting? |
|[ ]  Would the purpose of publishing findings of this research be to ***advocate*** for effective models, strategies, benchmark tools, or assessment tools for radiologic imaging rather than contributing novel, hypothesis-driven scientific knowledge? |
| *If the majority of boxes in this section are checked, this is likely Quality research and does not require an IRB submission. Please send research idea or protocol to Radiology Research Coordinator for review and final determination.* |

*Upon completion, please send this checklist and proposed research idea or proposal to* *radiologyresearch@unm.edu* *for further evaluation. If an IRB Submission is necessary, the Radiology Research Coordinator will respond to your email within 48 business hours. Please contact Radiology Research Coordinator with any questions (ext. 2-3826).*

\*ANY Study Code connected PHI Identifiers that can be directly linked to the study subject (see below).

\*\*Examples can include comparing software for metrics, looking at patient outcomes using binary coding with no storage of PHI, comparing outcomes of education methods or curricula.

PHI 18 Identifiers[[1]](#footnote-1)

1. Patient Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

1. UC Berkeley Human Research Protections Office. HIPAA PHI: List of 18 Identifiers and Definition of PHI. UC Regents, 2018. https://cphs.berkeley.edu/hipaa/hipaa18.html [↑](#footnote-ref-1)